

REMARKS

The Office Action dated December 28, 2004, has been received and reviewed. Claims 3-7 are pending in this application. Claims 3-7 stand rejected. Applicants have canceled Claims 5 and 7 without prejudice or disclaimer. Claim 8 has been added. Applicants respectfully request reconsideration of the application as amended herein and in view of the remarks below.

I. Claim Amendments

Applicants have amended Claims 3-4 to remove the term "about". Applicants have amended Claim 4 to independent format and include the recitations "A pharmaceutical formulation comprising an omeprazole composition fixed with a ratio of 5-methoxy and 6-methoxy isomers, wherein said ratio is determined by Fourier Transform Raman Spectroscopy and said ratio is a fixed ratio from 10 percent or less 5-methoxy and from 90 percent or more 6-methoxy". Support for this amendment may be found in tables 1A and 1B of exemplary ranges for omeprazole, with Table 1A listing possible ranges of 5/6-methoxy in API and Table 1B listing possible 5/6-methoxy in Drug Product. Applicants have canceled Claims 5 and 7 without prejudice or disclaimer. Applicants have added Claim 8 which depends from independent Claims 4.

II. New Matter

Applicants have canceled Claim 7 without prejudice or disclaimer thus mooting this rejection.

III. Claims Rejections – 35 U.S.C. § 112, second paragraph

Claims 4-5 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action alleges that the ratios claimed in Claims 4-5 can fall outside the scope of independent Claim 3. Applicants have amended Claim 4 to independent Claims to recite "A pharmaceutical formulation comprising an omeprazole composition fixed with a ratio of 5-methoxy and 6-methoxy isomers, wherein said ratio is determined by Fourier Transform Raman Spectroscopy and said ratio is a fixed ratio from 10 percent or less 5-methoxy and from 90 percent or more 6-methoxy". Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection to Claims 4. Claim 5 has been canceled thus mooting this rejection.

IV. Claims Rejections – 35 U.S.C. § 102(a)

Claims 3-4 and 6 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Junggren. Applicants respectfully traverse this rejection as set forth below.

Section 102(b) of Title 35 of the United States Code bars the issuance of a patent if "the invention was patented ... more than one year prior to the date of the application for patent in the United States." "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed.Cir.1987). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). "It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed.Cir.2002) (citations and internal quotation marks omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed.Cir.1999) (citations and internal quotation marks omitted).

Applicants submit that Junggren does not anticipate Claims 3-4 and 6 of the present application. Applicants note that Junggren only discloses a 5-methoxy isomer and does not disclose a 6-methoxy isomer. Applicants note that since Junggren never anticipated the 6-methoxy isomer, Junggren could never have produced a pharmaceutical formulation with a predetermined ratio of 5- and 6-methoxy isomers determined by Fourier Transform Raman Spectroscopy wherein the ratio is a fixed ratio from about 5% or less of the 5-methoxy isomer and from about 95% or more of the 6-methoxy isomer. Therefore, Junggren fails to teach each and every element of the present claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102 rejections to Claims 3-4 and 6.

Applicants further submit that Junggren does not anticipate Claims 3-4 and 6 of the present application nor are Claims 3-4 and 6 inherently disclosed by Junggren. Applicants note that the office action alleges that commercially available Prilosec anticipates the present invention as it purportedly discloses a ratio of 93:7 +/- 2% of the 6- vs. 5-methoxy isomers. Applicants note that this ratio is derived from the active pharmaceutical ingredient in

omeprazole, (See, specification, page 14, lines 17-22), and not a "pharmaceutical formulation" as recited in Claims 3-4 and 6. Applicants further note that the present specification discloses that the ratio in drug product of about 14:86 (\pm from about 3%), for the 5-methoxy and 6-methoxy respectively. Page 18, lines 13-14. Applicants note that the Claims 3-4 and 6 do not cover this range and are not inherently disclosed by Junggren. Thus, Applicants submit that Junggren does not anticipate the claims of the present application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102 rejections to Claims 3-4 and 6.

V. Double Patenting

Claims 3-6 are rejected under a non-statutory obvious-type double patenting rejection in view of Claims 19 to 29 and 32-34 of U.S. Patent 6,369,087, Claims 1-5 of U.S. Patent 6,268,385, Claims 9-16 of U.S. Patent 6,262,086, Claims 1-30 of U.S. Patent 6,653,329, and Claims 1-4 of U.S. Patent 6,667,324. Applicants note that the previous Office Action on Page 2, in the summary of the action notes that such claims were rejected under the judicially created doctrine of double patenting and as such, applicants believe that this rejection has been withdrawn and a new rejection under a non-statutory obvious-type double patenting rejection has taken place. Please feel free to contact the Applicant's representative if these assumptions are in error.

Applicants note that the cited patents do not recite that the pharmaceutical formulation is fixed and determined by Fourier Transform Raman Spectroscopy. However, in an effort to expedite prosecution of the present application, and in response to these rejections, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR § 1.321 with respect to Claims 19 to 29 and 32-34 of U.S. Patent No. 6,369,087, Claims 1-5 of U.S. Patent 6,268,385, Claims 9-16 of U.S. Patent 6,262,086, Claims 1-30 of U.S. Patent 6,653,329, and Claims 1-4 of U.S. Patent 6,667,324.

Applicants note that the submission of this terminal disclaimer in no way represents an acquiescence to the outstanding rejections or an acknowledgement that the subject matter of the pending claims is obvious over the claims of the cited patent and application.

Accordingly, Applicants respectfully submit that the filing of a terminal disclaimer has obviated the outstanding double-patenting rejections, and respectfully request withdrawal of the rejections on this basis.

ENTRY OF AMENDMENTS

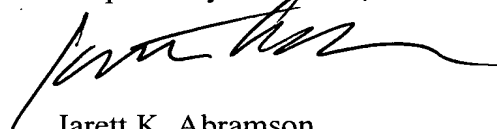
The amendments to the claims above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, Applicants believe that the amendments do not raise new issues or require a further search. Applicants further submit pursuant to 37 C.F. R. § 1.116, amendments after final presenting rejected claims in better condition for allowance may be admitted.

CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully submitted,



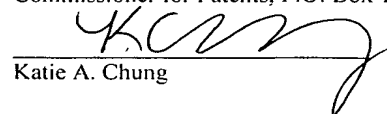
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